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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/765,324	12/24/1996	EUGEN KOREN	OMRF143-CIP2	5919

7590                    06/18/2002

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EXAMINER

DUFFY, PATRICIA ANN

ART UNIT	PAPER NUMBER
1645	37

DATE MAILED: 06/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. <b>08/765,324</b>	Applicant(s) <b>Koren et al</b>	
Examiner <b>Patricia A. Duffy</b>	Art Unit <b>1645</b>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Mar 18, 2002

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 48-51 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 48-51 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

6)  Other: \_\_\_\_\_

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*Response to Amendment*

1. The amendment filed 3-18-02 has been entered into the record. Claims 48-51 are pending and under examination.
2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

*Rejections Maintained*

3. The rejection of claims 48-51 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for reasons made of record.

In page 3 of the response, under amendments to the claims, Applicants representative states "Applicants agree that the claims should be limited to processing of a lipoprotein." However, this is not what the examiner has stated in the previous rejection of record. As previously set forth:

" It is noted that the written description in these passages directed to the apolipoprotein immunogen do not convey conception of: (a) the subgenus of solubilization with a reducing or denaturing agent as is instantly claimed; (b) removal of all self-aggregated and degraded material (i.e. free from self-aggregated and degraded material) by any means; © soluble lipoprotein (LDL, HDL or VLDL) as an immunizing material; (d) immunization with a apolipoprotein that is delipidated, reduced, carboxymethylated and

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solubilized with a reducing or denaturing agent that is free from aggregates and degradation products and (e) polyclonal antibodies."

and

"As to point (c), neither the passage at page 27, nor page 47 provides for conception of a lipoprotein so processed as an immunogen, nor how to utilize gels to remove all self aggregated and degraded from the lipoproteins (LDL, HDL or VLDL). The treatment regimen would destroy the lipoprotein as defined by the art. No purification of a lipoprotein free of self aggregated and degraded material can be made. The specification provides no written description of how to purify lipoproteins so treated."

Therefore the examiner did not set forth the position to which Applicants representative agrees. Applicants assert that the specification at page 26, line 20 to page 27 line 24 fully supports the claimed invention. This is not persuasive, Apo B-100 is an acronym that stands for "apolipoprotein" and not "lipoprotein". Further, the passage that applicants point to for support is not commensurate in scope with the claims. The currently crafted claims have no written description support in this passage. The passage is clearly directed to a specific species of apolipoprotein (Apo B-100), produced by a specific method. Applicants passage does not contemplate any other means. These claims have no written description support in this passage. Applicants attempt to broaden the disclosure by dropping limitations of this passage is improper and changes the scope of the disclosure as originally filed. Applicants assertion that the treatment regime would destroy the lipoprotein as defined by the art is irrelevant since what is claimed is the processing of the lipoprotein. It is noted that *the relied upon passage does not describe the processing of a lipoprotein, but of a specific apolipoprotein by a*

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*specific methodology.* No reference is made to a genus of apolipoproteins and no reference is made to a lipoprotein at all in this passage. No contemplation of alternative means are set forth, only a specific species of apolipoprotein by specific means. It is the written description of the specification that must support any additional claims and the relied upon passage fails to support processing of "lipoprotein" and is specifically directed to processing of a specific apolipoprotein (apo B-100) by a specifically disclosed method. Art equivalents are not contemplated within any of these steps. Applicants comments regarding the law are noted, however the same law indicates that if the claims change the scope of the disclosure they are considered new matter. Applicants reliance on other methods of isolation and purification of proteins is irrelevant here, when no such generic methods has been contemplated and Applicants later attempt to extract such from a narrow disclosure. The key issue here is conception by way of written description and the written description of this specification fails to support the instantly claimed invention. Applicants did not contemplate the generically claimed invention. The genus is not set forth in the original claims or in the passage to which applicants point for support. Applicants attempt to rely on well known methods is misplaced, because the central issue is conception of the claimed invention by way of written description in the specification as originally filed and the now claimed invention has no conception in the passage.

The rejection is maintained.

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***New Rejections Based on Amendment***

4. Claims 49 and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite from the use of the term "the desired apolipoprotein". This term lacks antecedent basis in claim 48.

***Status of Claims***

5. All claims stand rejected.

***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no

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event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

7. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Monday-Thursday and Saturday from 10:30 AM to 7:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D.  
June 17, 2002

*Patricia A. Duffy*  
Patricia A. Duffy, Ph.D.  
Primary Examiner  
Group 1600